

We Claim:

1. A biocompatible composite comprising a first  
5 biocompatible filamentous layer attached to a second  
biocompatible foam layer wherein the biocompatible foam  
is selected from the group consisting of gradient foams  
and channeled foams; wherein the gradient foam has a  
first location and a second location wherein the  
10 biocompatible gradient foam has a substantially  
continuous transition in at least one characteristic  
selected from the group consisting of composition,  
stiffness, flexibility, bioabsorption rate and pore  
architecture from the first location to the second  
15 location of said biocompatible gradient foam and the  
channeled foam has a first surface and a second surface  
with channels therein.

2. The biocompatible composite of claim 1 wherein the  
20 biocompatible foam is bioabsorbable.

3. The biocompatible composite of claim 1 wherein the  
biocompatible filamentous layer is bioabsorbable.

25 4. The biocompatible composite of claim 1 wherein the  
biocompatible composite is made from a bioabsorbable  
polymer selected from the group consisting of aliphatic  
polyesters, poly(amino acids), copoly(ether-esters),

polyalkylenes oxalates, polyamides,  
poly(iminocarbonates), polyorthoesters, polyoxaesters,  
polyamidoesters, polyoxaesters containing amine groups  
poly(anhydrides), polyphosphazenes, biopolymers and  
blends thereof.

5        5.    The biocompatible composite of claim 4 wherein the  
         bioabsorbable polymer is an aliphatic polyester.

10       6.    The biocompatible composite of claim 5 wherein the  
         aliphatic polyester is selected from the group  
         consisting of homopolymers and copolymers of lactide,  
         lactic acid, glycolide, glycolic acid),  $\epsilon$ -caprolactone,  
         p-dioxanone (1,4-dioxan-2-one), trimethylene carbonate  
15       (1,3-dioxan-2-one), alkyl derivatives of trimethylene  
         carbonate,  $\delta$ -valerolactone,  $\beta$ -butyrolactone,  $\gamma$ -  
         butyrolactone,  $\epsilon$ -decalactone, hydroxybutyrate,  
         hydroxyvalerate, 1,4-dioxepan-2-one, 1,5,8,12-  
         tetraoxacyclotetradecane-7,14-dione), 1,5-dioxepan-2-one,  
20       6,6-dimethyl-1,4-dioxan-2-one and polymer blends thereof.

7.    The biocompatible composite of claim 5 wherein the  
         aliphatic polyester is an elastomer.

25       8.    The biocompatible composite of claim 7 wherein the  
         elastomer is selected from the group consisting of  
         copolymers of  $\epsilon$ -caprolactone and glycolide; copolymers  
         of  $\epsilon$ -caprolactone and (L)lactide, copolymers of p-

dioxanone (1,4-dioxan-2-one) and (L)lactide, copolymers  
of  $\epsilon$ -caprolactone and p-dioxanone, copolymers of p-  
dioxanone and trimethylene carbonate, copolymers of  
trimethylene carbonate and glycolide, copolymer of  
5 trimethylene carbonate and (L)lactide and blends  
thereof.

9. The biocompatible composite of claim 5 wherein  
additionally present as a constituent of the  
10 biocompatible foam is a second aliphatic polyester.

10. The biocompatible composite of claim 5 wherein  
additionally present as a constituent of the  
15 biocompatible filamentous layer is a second aliphatic  
polyester.

11. The biocompatible composite of claim 4 wherein the  
biocompatible gradient foam has a substantially  
continuous transition in composition from the first  
20 location to the second location.

12. The biocompatible composite of claim 11 wherein the  
biocompatible gradient foam has a substantially  
continuous transition in composition from a first ratio  
25 of at least two different aliphatic polyesters to a  
second ratio of said at least two different aliphatic  
polyesters from the first surface to the second surface.

13. The biocompatible composite of claim 4 wherein the biocompatible gradient foam has a substantially continuous transition in stiffness from the first location to the second location.

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14. The biocompatible composite of claim 4 wherein the biocompatible gradient foam has a substantially continuous transition in bioabsorption rate from the first location to the second location.

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15. The biocompatible composite of claim 4 wherein the biocompatible gradient foam has a substantially continuous transition in flexibility from the first location to the second location.

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16. The biocompatible composite of claim 4 wherein the biocompatible gradient foam has a substantially continuous transition in architecture from the first location to the second location.

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17. The biocompatible composite of claim 16 wherein the biocompatible gradient foam has a substantially continuous transition in architecture from a substantially spherical pore shape to a columnar pore shape from the first location to the second location.

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18. The biocompatible composite of claim 16 wherein the substantially spherical pore's size is from about 30  $\mu\text{m}$  to about 150  $\mu\text{m}$ .

5 19. The biocompatible composite of claim 16 wherein the columnar pore's diameter is from about 100  $\mu\text{m}$  to about 400  $\mu\text{m}$  with a length to diameter ratio of at least 2.

10 20. The biocompatible composite of claim 1 wherein also present in the biocompatible composite is a therapeutic agent.

15 21. The biocompatible composite of claim 1 wherein additionally present is an agent is selected from the group consisting of antiinfectives, hormones, analgesics, anti-inflammatory agents, growth factors, chemotherapeutic agents, anti-rejection agents prostaglandins, RDG peptides and combinations thereof.

20 22. The biocompatible composite of claim 21 wherein the growth factor is selected from the group consisting of bone morphogenic proteins, bone morphogenic-like proteins, epidermal growth factor, fibroblast growth factors, platelet derived growth factor, insulin like growth factor, transforming growth factors, vascular  
25 endothelial growth factor and combinations thereof.

23. The biocompatible composite of claim 1 wherein the biocompatible compatible foam is filled with a biocompatible material selected from the group consisting of bioabsorbable synthetic polymers, biocompatible, bioabsorbable biopolymers, biocompatible ceramic materials and combinations thereof.

24. The biocompatible composites of claim 1 wherein the channeled foam has channels with an average length of at least 200  $\mu\text{m}$ .

25. The biocompatible composites of claim 24 wherein the channels extend substantially from said first surface to said second surface.

26. The biocompatible composite of claim 1 wherein the biocompatible foam has interconnected pores formed from a composition containing in the range of from about 30 weight percent to about 99 weight percent  $\epsilon$ -caprolactone repeating units.

27. The biocompatible composite of claim 26 wherein the  $\epsilon$ -caprolactone repeating units are copolymerized with a comonomer selected from the group consisting of lactide, lactic acid, glycolide, glycolic acid), p-dioxanone (1,4-dioxan-2-one), trimethylene carbonate (1,3-dioxan-2-one), alkyl derivatives of trimethylene carbonate,  $\delta$ -valerolactone,  $\beta$ -butyrolactone,  $\gamma$ -butyrolactone,  $\epsilon$ -

decalactone, hydroxybutyrate, hydroxyvalerate, 1,4-dioxepan-2-one, 1,5,8,12-tetraoxacyclotetradecane-7,14-dione), 1,5-dioxepan-2-one, 6,6-dimethyl-1,4-dioxan-2-one and polymer blends thereof.

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28. The biocompatible composite of claim 26 having a first location and a second location wherein the biocompatible foam has a substantially continuous transition in at least one characteristic selected from the group consisting of composition, stiffness, flexibility, bioabsorption rate and pore architecture from the first location to the second location of said biocompatible foam.

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29. The biocompatible composite of claim 26 wherein the interconnecting pores have a pore size in the range from about 10  $\mu\text{m}$  to about 200  $\mu\text{m}$ .

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30. The biocompatible composite of claim 26 wherein the biocompatible foam has a porosity of in the range of from about 20 to about 98 percent.

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31. The biocompatible composite of claim 26 wherein the biocompatible foam has channels.

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32. The biocompatible composites of claim 31 wherein the channels have an average length of at least 200  $\mu\text{m}$ .

33. The biocompatible composite of claim 26 wherein the substantially spherical pore's size is from about 30  $\mu\text{m}$  to about 150  $\mu\text{m}$ .

5 34. The biocompatible composite of claim 26 wherein the columnar pore's diameter is from about 30  $\mu\text{m}$  to about 400  $\mu\text{m}$  with a length to diameter ratio of at least 2.

10 35. The biocompatible composite of claim 26 wherein also present in the biocompatible foam is a therapeutic agent.

15 36. The biocompatible composite of claim 1 wherein the biocompatible foam is formed with an insert within the biocompatible foam.

20 37. The biocompatible composite of claim 36 wherein the insert is selected from the group consisting of films, scrims, woven textiles, knitted textiles, braided textiles, orthopedic implants, tubes and combinations thereof.

25 38. The biocompatible composite of claim 1 wherein the biocompatible composite is formed into a three-dimensional shaped structure.

39. The biocompatible composite of claim 38 wherein the three-dimensional shaped structure is selected from the



group consisting of tubular shapes, branched tubular shapes, spherical shapes, hemispherical shapes, three-dimensional polygonal shapes, ellipsoidal shapes, toroidal shapes, conical shapes, frusta conical shapes, pyramidal shapes, both as solid and hollow constructs and combination thereof.

40. A method for the repair or regeneration of tissue comprising contacting cells with a biocompatible composite comprising a first biocompatible filamentous layer attached to a second biocompatible foam layer wherein the biocompatible foam is selected from the group consisting of gradient foams and channeled foams; wherein the biocompatible gradient foam has a first location and a second location wherein the biocompatible gradient foam has a substantially continuous transition in at least one characteristic selected from the group consisting of composition, stiffness, flexibility, bioabsorption rate and pore architecture from the first location to the second location of said biocompatible gradient foam and the channeled foam has a first surface and a second surface with channels therein.

41. The method of claim 40 wherein the biocompatible composite is bioabsorbable.

42. The method of claim 40 wherein the biocompatible composite is made from a bioabsorbable polymer selected

from the group consisting of aliphatic polyesters,  
poly(amino acids), copoly(ether-esters), polyalkylenes  
oxalates, polyamides, poly(iminocarbonates),  
polyorthoesters, polyoxaesters, polyamidoesters,  
5 polyoxaesters containing amine groups poly(anhydrides),  
polyphosphazenes, biopolymers and blends thereof.

43. The method of claim 42 wherein the bioabsorbable  
polymer is an aliphatic polyester.

10 44. The method foam of claim 43 wherein the aliphatic  
polyester is selected from the group consisting of  
homopolymers and copolymers of lactide, lactic acid,  
glycolide, glycolic acid),  $\epsilon$ -caprolactone, p-dioxanone  
15 (1,4-dioxan-2-one), trimethylene carbonate (1,3-dioxan-  
2-one), alkyl derivatives of trimethylene carbonate,  $\delta$ -  
valerolactone,  $\beta$ -butyrolactone,  $\gamma$ -butyrolactone,  $\epsilon$ -  
decalactone, hydroxybutyrate, hydroxyvalerate, 1,4-  
dioxepan-2-one, 1,5,8,12-tetraoxacyclotetradecane-7,14-  
20 dione), 1,5-dioxepan-2-one, 6,6-dimethyl-1,4-dioxan-2-one  
and polymer blends thereof.

45. The method of claim 44 wherein the aliphatic  
polyester is an elastomer.

25 46. The method of claim 40 wherein cells are seeded  
onto the biocompatible composite.

47. The method of claim 44 wherein cells are seeded onto the biocompatible composite.

5 48. The method of claim 40 wherein the biocompatible composite is implanted in an animal and contacted with cells.

10 49. The method of claim 44 wherein the biocompatible composite is implanted in an animal and contacted with cells.

15 50. The method of claim 40 wherein the biocompatible composite is seeded with cells and the biocompatible composite and cells are placed in a cell culturing device and the cells are allowed to multiply on the biocompatible composite.

20 51. The method of claim 44 wherein the biocompatible composite is seeded with cells and the biocompatible composite and cells are placed in a cell culturing device and the cells are allowed to multiply on the biocompatible composite.

25 52. The method of claim 40 wherein the cells are selected from the group consisting of pluripotent cells, stem cells, precursor cells and combinations thereof.

53. The method of claim 40 wherein the cells are selected from the group consisting of myocytes, adipocytes, fibromyoblasts, ectodermal cell, muscle cells, osteoblast, chondrocyte, endothelial cells, fibroblast, pancreatic cells, hepatocyte, bile duct cells, bone marrow cells, neural cells, genitourinary cells and combinations thereof.

54. The method of claim 40 wherein the biocompatible composite contains an agent selected from the group consisting of antiinfectives, hormones, analgesics, anti-inflammatory agents, growth factors, chemotherapeutic agents, anti-rejection agents, prostaglandins, RDG peptides and combinations thereof.

55. A method of claim 40 wherein the biocompatible composite is formed from a composition containing in the range of from about 30 weight percent to about 99 weight percent  $\epsilon$ -caprolactone repeating units.

56. The method foam of claim 55 wherein the  $\epsilon$ -caprolactone repeating units are polymerized with a comonomer selected from the group consisting of homopolymers and copolymers of lactide, lactic acid, glycolide, glycolic acid), p-dioxanone (1,4-dioxan-2-one), trimethylene carbonate (1,3-dioxan-2-one), alkyl derivatives of trimethylene carbonate,  $\delta$ -valerolactone,  $\beta$ -butyrolactone,  $\gamma$ -butyrolactone,  $\epsilon$ -decalactone,

hydroxybutyrate, hydroxyvalerate, 1,4-dioxepan-2-one, 1,5,8,12-tetraoxacyclotetradecane-7,14-dione), 1,5-dioxepan-2-one, 6,6-dimethyl-1,4-dioxan-2-one and polymer blends thereof.

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57. The method of claim 55 wherein cells are seeded onto the biocompatible composite.

58. The method of claim 55 wherein the biocompatible foam is implanted in an animal and contacted with cells.

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59. The method of claim 55 wherein the biocompatible composite is seeded with cells and the biocompatible composite and cells are placed in a cell culturing device and the cells are allowed to multiply on the biocompatible composite.

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60. The method of claim 59 wherein the cells are selected from the group consisting of pluripotent cells, stem cells, precursor cells and combinations thereof.

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61. The method of claim 59 wherein the cells are selected from the group consisting of myocytes, adipocytes, fibromyoblasts, ectodermal cell, muscle cells, osteoblast, chondrocyte, endothelial cells, fibroblast, pancreatic cells, hepatocyte, bile duct cells, bone marrow cells, neural cells, genitourinary cells and combinations thereof.

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